In support of the Restriction Requirement, the Examiner alleges that "[t]he inventions of Groups I-IV (*sic.*) are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success." *See* page 2 of the Restriction Requirement.

The Examiner has also required an election of species, which are listed as sub-elements I-V at pages 2-4 of the Office Action.

Traversal of the Restriction Requirement:

Applicants elect, with traverse, Group I, drawn to a method for treating a tumor. Applicants traverse the Restriction Requirement on the grounds that the Examiner has not provided a proper basis for restriction, and that search and examination of the claims of Groups I-VI do not impose an undue burden upon the Examiner. More specifically, the restriction is improper since the methods set forth in each of the restricted groups are found in the proper Markush group of claim 46.

M.P.E.P. § 803.02 discusses restriction practice in the context of Markush groups and notes,

> "[i]t is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention.... Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility" (citations omitted).

Furthermore, under M.P.E.P. § 803, restriction is proper "only if [the Groups of claims] are able to support separate patents and they are either independent or distinct." M.P.E.P. 803 continues by noting that, "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." M.P.E.P.

803. Thus, there are **two** burdens the Examiner must meet for a proper restriction requirement. First, the inventions must be independent or distinct; second, there must additionally be a serious burden on the examiner before a restriction is appropriate. The Examiner has failed to satisfy these two burdens.

The objective evidence clearly is in favor of Applicant's position that the restriction requirement is wholly improper and unreasonable. In particular, not a single Group listed by the Examiner contains claims that are distinguishable from the claims of the other Groups (each Group consists of claims 1-54). This commonality, alone, should negate any contention by the Examiner that a search cannot be made without serious burden. However, there is still additional evidence that illustrates the improper nature of the restriction requirement. For example, Applicant's position is buttressed by the fact that each of the six restricted Groups are all classified in the same class, class 424. Furthermore, the claims in each Group belong to the same subclass; namely, 1320.1+, 178.1+, and 94.1+.

The primary difference between the Groups of claims is in regard to the targeted tissues, which are found in the Markush group of dependent claim 46. The elements of the Markush group share substantial structural features, for example, targeting protein recognition sites, which would enable a target protein to be directed to such a protein recognition site. Because the Markush group is indeed proper, coupled with the fact that this Markush group is part of a dependent claim, the restriction requirement cannot stand. If, for example, Applicant decided to cancel claim 46, the Examiner would have no basis from which to formulate the different Groups.

Applicant submits that if there is to be any parsing of the claims in the instant application, this should be effected only by an election of species and **not** through a restriction of invention. In fact, MPEP § 803.02 – which speaks directly to Markush-type claims – only sanctions a provisional election of *species* when a Markush-type claim is involved. This is the case even when "two or more of the members [of the Markush group] are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s)." *See* MPEP § 803.02. Accordingly, at the very

least, the Examiner should treat Applicant's election of Group I as an election of one species. Pursuant to MPEP § 803.02, this species will then be examined fully. Then, if no prior art anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended.

Indeed, the former Group Director of 120, John Terapane, has recognized that this is the proper course of action, as reflected in his comments before the Annual Conference on PTO Law and Practice, (December 3, 1992):

> [W]hen a claim containing a Markush group is considered to contain more than one patentably distinct invention, the examiner may make a restriction requirement under 35 USC §121. This may take the form of identifying the groups of elements that the examiner considers to be patentably distinct inventions or species, together with a requirement to elect. This requirement may be coupled with a rejection, based on judicial precedent, if the claim contains an improper Markush group. The elected invention is examined, and if there is no rejection based on an improper Markush group, the procedure of MPEP 803.02 is followed - the claim is examined until one species is found which renders the claim unpatentable or the entirety of the claimed subject matter is found to be patentable. [Emphasis added.]

Election of Species:

Applicant also elects the following species: I. Target proteins – fusion protein (claim 3); II. Enzymes – Carboxyesterase (claim 6); III. Prodrug – CPT-11 (claims 7,8); IV. Therapeutic agent – camptothecin (claim 45); and V. Target site – CEA antigen (disclosed in the specification at, *e.g.*, page 16, lines 18-20). Applicants submit that the election of species requirement is the proper procedure to follow, in light of the foregoing remarks concerning the restriction requirements. Accordingly, Applicant has already elected a species within the Markush group by virtue of election of the invention of Group I, drawn to a method for treating a tumor and the further specification of targeting agent, enzyme, prodrug, drug and tumor antigen.

Conclusion

For the foregoing reasons, Applicant respectfully requests withdrawal of the Restriction Requirement. An action on the merits conforming to the foregoing is awaited. Should the Examiner have any questions or comments regarding the pending

application or this Response, the Examiner is courteously invited to telephone the undersigned counsel at the telephone number shown below.

Respectfully submitted,

May 30, 2000
Date

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